Long-term Outcomes of Endodontic Treatment Performed with Resilon/Epiphany

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Abstract

Introduction: Resilon (Resilon Research LLC, Madison, CT) with Epiphany Sealer (Pentron Clinical Technologies, Wallingford, CT) was introduced into the market in 2004 as a new method of root canal obturation. This material as well as the traditionally used gutta-percha with AH Plus sealer (Dentsply Maillefer, Tulsa, OK) were in use over a 9-year span in the University of North Carolina endodontic clinics. Although Resilon was initially thought to create a "monoblock" seal between the material and the canal, *in vitro* studies later suggested this concept not to be true. The long-term outcome of Resilon using a validated radiographic index and a systematic approach has not been reported. The purpose of this retrospective cohort study was to radiographically evaluate the outcome of Resilon/Epiphany-treated root canals compared with traditional gutta-percha/AH Plus. **Methods:** One hundred twenty-five teeth were radiographically evaluated using the periapical index; 80 were treated with Resilon and 45 with gutta-percha. Age, sex, tooth position, and number of months to follow-up were documented, and a multivariate analysis with odds ratio was performed. **Results:** Resilon-treated teeth were 5.3 times more likely to have a periapical index of 3 to 5 at follow-up compared with gutta-percha ($P = .009$). Teeth presenting with preoperative lesions, regardless of the material used, were also more likely to present with a lesion at follow-up ($P = .04$). **Conclusions:** Teeth obturated with Resilon were more likely to present with a lesion at follow-up compared with gutta-percha obturated teeth after controlling for the presence of a preoperative lesion and the length to follow-up. *(J Endod 2019;45:507–512)*

Key Words

Apical periodontitis, endodontic treatment, gutta-percha, healing, nonsurgical root canal treatment, outcomes, Resilon

Significance

Many endodontic patients have been treated with Resilon/Epiphany after preliminary results showed favorable results. We evaluated the long-term outcomes of cases treated with Resilon or gutta-percha using an adequately powered sample with objective criteria. Gutta-percha was associated with a significantly better outcome than Resilon.

Gutta-percha is 1 of the most popular obturation materials in practice today (1). It is composed of 20% gutta-percha, 66% zinc oxide, 11% radiopacifier, and 3% plasticizer (2). Although gutta-percha has multiple favorable properties, such as biocompatibility, thermoplasticity, and ease of removal (3), there is a critical element that gutta-percha lacks—direct adhesion to the canal wall (4).

Different obturation materials have been introduced into the market, some claiming to have superior if not equivalent results to gutta-percha. Resilon (Resilon Research LLC, Madison, CT) was introduced in 2004 as a thermoplastic synthetic polymer alternative to gutta-percha. It is composed primarily of a parent polymer polycaprolactone (25%–40%), which is a biodegradable aliphatic polyester. The remaining fillers are bioactive glass, bismuth oxychloride, and barium sulfate (5). The sealer, Epiphany Sealer (Pentron Clinical Technologies, Wallingford, CT), is a dual curable resin composite sealer. When Epiphany sealer is used with Resilon, a bond is said to be created to both the canal wall and the core canal filling material. This type of obturation system is considered a single entity, which forms a "monoblock" (6). This method claimed to have less leakage than the traditional gutta-percha with sealer (7).

Although this obturation system had received much support after its introduction, there are several undesirable properties that have been discovered over time, including its degradation, lack of a true monoblock, shrinkage of the sealer, and lack of antibacterial properties. Polycaprolactone in Resilon is biodegradable and susceptible to enzymatic hydrolysis by endodontic bacteria and fungi (8). Through scanning electron microscopy, it was shown that gaps were present between Resilon and the Epiphany sealer (9). This indicated that a hermetic apical seal, which Resilon based its superiority on, was not occurring (9). When attempting to bond any material to the narrow surfaces of a root canal, the C factor, the ratio of bonded surface area (SA) to the unbonded SA in a cavity, must be evaluated (10). In a long narrow root canal, the unbonded SA becomes smaller and has insufficient stress relief, creating a high probability that multiple areas will debond. The C factor in a canal has been shown to be extremely high (over 1000) when compared with indirect intracoronal restorations (10). It is doubtful that the Resilon sealer bonds can resist this shrinkage stress (11). In addition to studies on the bonding effectiveness of Resilon, its antibacterial properties have also been reviewed. An *in vitro* study showed that Resilon did not display any antibacterial properties,

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whereas gutta-percha inhibited *Fusobacterium nucleatum* and *Actinomyces naeslundii* (12).

In studies evaluating primary endodontic treatment success, teeth with preoperative radiographic lesions consistently have lower success rates than those without any periapical pathosis (13). The outcome of treatment using traditional gutta-percha obturation techniques is dependent on whether an apical radiolucency is present preoperatively. In cases with no lesion, success ranges from 89.5%–95.4%. In teeth with apical radiolucencies, success ranges from 75.5%–82.7% (14, 15). The healing rate of Resilon versus gutta-percha in a preliminary *in vivo* 12-month minimum follow-up was found to have no significant difference from that of gutta-percha (16). Another earlier retrospective study with 12- to 25-month follow-ups also found indistinguishable differences in clinical outcome between the 2 obturation methods (17).

However, a more recent study with longer outcome periods found that Resilon obturated teeth had a 5.7 times greater chance of failure when compared with gutta-percha (18). This material was used at that dental school for a 5-year span, and the average follow-up for Resilon was 5.8 years. In that study, cases were included retrospectively if they had a radiographic and clinical recall examination performed with adequate documentation. There was no attempt to invite treated patients to attend a systematic study of outcomes. At our institution, Resilon was used for 9 years. Therefore, this study sought to determine the outcome of treatment using Resilon versus gutta-percha obturation after a longer outcome period and after specifically inviting an adequately powered sample of patients to come back for examination. The validated periapical index (PAI) was also used for objective outcomes assessment.

Methods

Institutional review board approval for this retrospective clinical study was obtained at the University of North Carolina (UNC). Our inclusion criteria were patients who were 18 years or older, had completed root canal treatment (dental codes D3310, D3320, or D3330) during the period of August 2004 to August 2013, and had been treated in the UNC predoctoral and postgraduate endodontic clinics. These patients were identified through a search of the electronic patient records. Our exclusion criteria were patients whose dental records did not include a radiograph immediately after the original root canal treatment or did not specify which material was used for obturation (Resilon or gutta-percha).

A review of patient records indicated that 7376 patients were seen for primary root canal treatment during the specified period in the UNC predoctoral and graduate endodontic clinic. Five hundred eighty patients who qualified for the study were randomly selected, and telephone calls were made in an attempt to contact the patient. Randomization was done by using a randomizing website (https://www.randomizer.org). If there was no answer, a scripted voice message was left. If a secondary number was on file, that too was called. One hundred twenty-five (21.6%) patients agreed to come into the endodontic clinic for a follow-up visit and consented to be a part of the study.

Sample Size Estimation

After a preliminary sample of 50 teeth were assessed, a sample size estimation using NQuery (Statistical Solutions Ltd, Cork, Ireland) indicated that a chi-square test with a .05 2-sided significance level would have greater than 80% power to detect a 25% difference in healing between Resilon and gutta-percha using an unequal sample size ratio of 1.5. An unequal sample size was used because Resilon-treated cases were more numerous than gutta-percha cases during the time frame studied.

Follow-up

The follow up examination was performed under supervision of board-certified endodontists. Patient age, sex, tooth type (anterior vs posterior), and the obturation material used (Resilon or gutta-percha) were recorded, and the presence or absence of a preoperative periapical lesion was also documented. Two digital periapical images of each tooth were collected for evaluation using DenOptix QST #2 Photostimulable Phosphor Plates (Gendex, Hatfield, PA) with a Rinn XCP precision instrument (Rinn Corp, Elgin, IL). The plates were scanned into a DenOptix QST Class 1 Laser Scanner (Gendex). The first image was taken immediately after root canal treatment and the second at the most recent follow-up. The time from the initial root canal treatment to the most recent follow-up was recorded to the nearest month. At the recall visit, diagnostic tests were performed on the treated tooth, and patient symptoms were recorded.

Recording of Data

The information gathered at the follow-up examination was recorded during the appointment on an assessment form specific for each patient. Before the periapical images were evaluated, 2 board-certified endodontists (P.T. and H.W.) were calibrated to interpret the images using Orstavik's PAI calibration kit of 100 periapical radiographs (19).

The posttreatment and follow-up images were viewed and assessed under similar lighting and monitor screens. The examiners (P.T. and H.W.) were masked to the material used for obturation. They evaluated and ranked the radiograph shortly after the follow-up examination of each tooth according to the PAI criteria. Multirooted teeth were given 1 score (ie, the highest score of any of the roots). The interexaminer reliability was found to be in nearly perfect agreement ($\kappa = 0.87$). The intraexaminer reliability was also excellent ($\kappa = 0.90$). If there was disagreement greater than 1 rank, the 2 examiners met later to discuss the images until consensus agreement was reached.

Outcome Assessment

The radiographic data were dichotomized into no lesion present (PAI scores of 1 and 2) and lesion present (PAI scores of 3, 4, and 5).

Statistical Analysis

Bivariate analysis to compare the obturation materials was performed using the chi-square test for nominal variables and the Wilcoxon rank sum test for continuous variables. Proc-Genmod (SAS Institute Inc, Cary, NC), as a conditional logistic regression analysis, was used to assess the effect of material, the months to follow-up, the presence of a preoperative lesion, age, sex, and tooth position on the presence of a follow-up lesion. The interaction term of preoperative lesion with group was included in the initial model and removed in the final model because the interaction term was not statistically significant ($P = .23$). The odds ratio from the conditional logistic regression with a 95% confidence interval was also calculated. The level of significance was established as $P < .5$.

Results

A total of 125 subjects were included in the study, and the sample characteristics are depicted in Table 1. Each patient contributed only 1 tooth. Eighty subjects had Resilon as the obturation material, and 45 had gutta-percha. Forty-three percent of the subjects had presented with a preoperative lesion, and 36% had a follow-up lesion. There were no statistically significant differences between the 2 groups (Resilon vs gutta-percha) with respect to sex, tooth position, or age

TABLE 1. Characteristics for All Subjects and a Comparison of the 2 Obturation Materials

	All, *n*, %	Resilon, *n*, %	Gutta-percha, *n*, %	*P* value
Sex				.73
Male	53, 42.4	33, 41.3	20, 44.4	
Female	72, 57.6	47, 58.7	25, 55.6	
Tooth position				.77
Anterior	26, 20.8	16, 20	10, 22.2	
Posterior	99, 79.2	64, 80	35, 77.8	
Preoperative lesion				.015
Yes	54, 43.2	41, 51.3	13, 28.9	
No	71, 56.8	39, 48.7	32, 71.1	
Follow-up lesion				.0004
Yes	45, 36	38, 47.5	7, 15.6	
No	80, 64	42, 52.5	38, 84.4	

	N	All Median	IQR	*n*	Resilon Median	IQR	*n*	Gutta-percha Median	IQR	*P* value
Age	125	56	19	80	57.5	19.5	45	54	20	.70
Months to follow-up	125	49	63	80	62.5	62	45	26	19	<.0001

IQR, interquartile range.

(Table 1). The 2 materials were significantly different with respect to the presence of a preoperative lesion and months to follow-up (Table 1). Subjects with Resilon had a higher percentage of preoperative lesions and a longer time to follow-up. Follow-up periapical radiographs of Resilon- and gutta-percha–treated teeth showed varying levels of healing (Fig. 1*A*–*F*).

In the multivariate analysis, the presence of a preoperative lesion and the type of material used for obturation remained statistically significant predictors of outcome when controlling for age, sex, tooth position, and months to follow-up (Table 2). Both the lack of an initial lesion and having gutta-percha were protective (ie, individuals with an initial lesion and those receiving Resilon were more likely to have a follow-up lesion). The adjusted odds ratio showed that subjects (teeth) with Resilon were 5.3 times more likely to have a lesion at follow-up than those treated with gutta-percha.

Discussion

This study represents the longest outcome data available for a comparison of Resilon and gutta-percha materials. The use of Resilon was introduced at UNC, and its use was continued for almost a decade. The sensitive technique of the bonded material was taught to both the faculty and students at UNC at the introduction of the material into clinical practice. This puts this data set at a unique position to provide a good level of evidence for the long-term outcome of root canal obturation with Resilon.

All subjects treated at UNC were treated using a relatively consistent protocol (for Resilon and gutta-percha) that was taught to students by instructors who were familiar with both obturation techniques. From the 580 subjects who qualified for inclusion, 125 subjects had a follow-up visit for a follow-up rate of 21.6%, which is comparable with other long-term outcome studies performed in the United States (20). The minimum follow-up for both materials was 12 months because it has been shown that initiated healing can be observed in 89% of cases without preoperative lesions in as early as 1 year (21). The average follow-up period for Resilon and gutta-percha was 12.4 years and 12.1 years, respectively. Although both Resilon and gutta-percha were in use from 2004 to 2013, gutta-percha was more common clinically in the later years. Resilon patients who agreed to take part in the study were primarily from the beginning of Resilon's implementation as well as the last year of its use, which explains why the follow-up for gutta-percha was on average less than Resilon.

The primary outcome for this study was radiographic healing. This was established by using the validated PAI to evaluate the periapical structure of the treated teeth (22). We chose to dichotomize the data into either a lesion not being present (PAI 1 or 2) or a lesion being present (PAI 3, 4, or 5). By dichotomizing our data, these ranks could be sorted into 2 distinctive and radiographically separate groups. The multivariate analysis, shown in Table 2, controlled for all other explanatory variables. Resilon-treated teeth were more likely to have a periapical lesion at follow-up than gutta-percha. This difference was statistically significant ($P = .009$), and the adjusted odds ratio indicated that Resilon-treated teeth were 5.3 times more likely to have a lesion at follow-up when compared with gutta-percha even after controlling for the presence of a preoperative lesion and the length to follow-up. The findings that a tooth with a preoperative lesion, regardless of the material used, was more likely to have a follow-up lesion ($P = .04$) agrees with many classic and current studies that preoperative pathosis has a negative effect on treatment success (14, 20, 23, 24).

Regardless of the positive findings reported in *in vitro* studies of Resilon (7, 25), clinical studies should influence the decision of which materials to use clinically. Resilon and gutta-percha showed an indistinguishable difference in healing outcome in a 12- to 25-month retrospective follow-up study (17). That study evaluated 103 teeth, 68 of which were evaluated between 18 and 25 months. The other 35 were evaluated after 12–18 months. The only other long-term outcome study on Resilon was a recently published study in which the follow-up was 5.6 years on average (18). There were similarities in the study design between these 2 articles and ours. Both our study and the study by Cotton et al (17) used PAI to score the periapical images of teeth at the time of treatment and at the follow-up. Gutta-percha was used as a control for comparison with Resilon in our study and the studies by Cotton et al (17) and Barborka et al (18). A difference between the study by Barborka et al and our study was how they radiographically assessed healing. Instead of using the validated and objective PAI, they chose to evaluate the images side by side with a study-derived definition of success. They also did not actively recruit patients with phone calls or use a power analysis to determine the amount of cases needed in each group.

There are potentially several reasons for the increased proportion of postoperative lesions with Resilon. The first being the composition of the material. Polycaprolactone, the biodegradable polyester

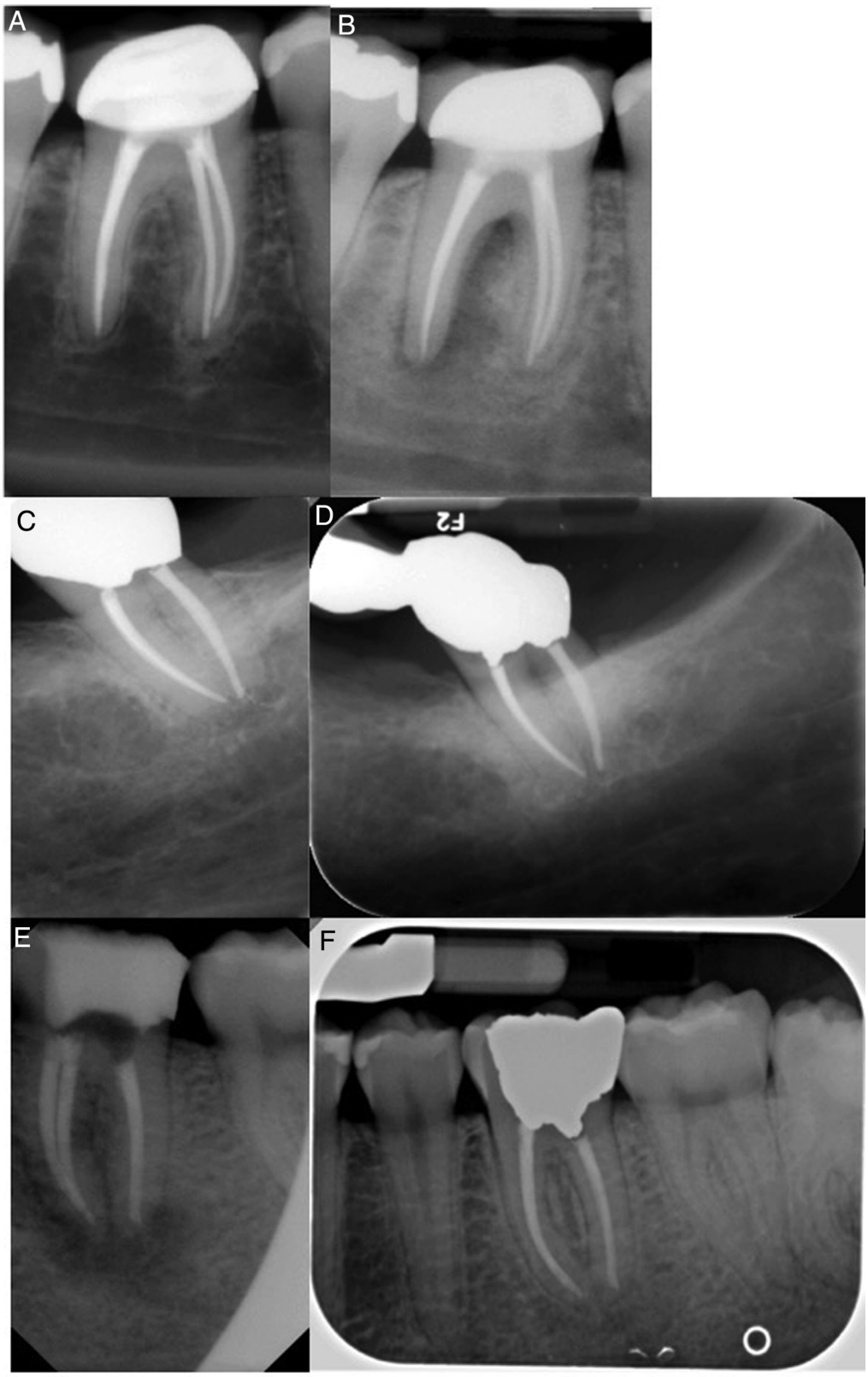

Figure 1. (*A*, *C*, and *E*) Posttreatment and (*B*, *D*, and *F*) follow-up radiographs of (*A*) Resilon-treated tooth #30 with a PAI score of 1, (*B*) 3.5-year follow-up of tooth #30 with a PAI score of 5, (*C*) Resilon-treated tooth #18 with a PAI score of 3, (*D*) 11.9-year follow-up of tooth #18 with a PAI score of 1, (*E*) gutta-percha–treated tooth #19 with a PAI score of 4, and (*F*) 1.3-year follow-up of tooth #19 with a PAI score of 1.

TABLE 2. Odds Ratio from the Multivariate Analysis of the Presence of a Follow-up Lesion

Variable	Estimate	Error	95% CI	*P* value
Preoperative lesion	−0.87	0.42	−1.7 to −0.05	.04
Material	−1.67	0.64	−2.9 to −0.42	.009
Months to follow-up	−0.16	0.24	−0.6 to 0.3	.49
Age	−0.02	0.02	−0.05 to 0.02	.34
Sex	−0.56	0.49	−1.5 to 0.39	.25
Tooth position	−0.10	0.48	−1.04 to 0.84	.84

CI, confidence interval.

A negative estimate indicates a protection factor.

compromising a majority of Resilon, was suggested to result in severe surface pitting and erosion (26). The adhesive property of Resilon was also shown to not be as predictable in the long narrow canal, even with aid from a surgical microscope. The effectiveness of the bond was also a concern because it is difficult to avoid overthinning of the adhesive (27). In an *in vitro* study, the presence of gaps along the core/sealer/dentin interface was shown to potentially create an environment for leakage and reinfection (9). A retrospective study used data from periapical radiographs and cone-beam computed tomographic scans to examine various factors affecting the outcome of root canal treatment. The density of the root filling was identified in both periapical and cone-beam computed tomographic images as a predictor that significantly influenced the treatment outcome (28).

While recalling patients, we noticed that despite the highly dense and radiopaque appearance of Resilon-treated teeth (Fig. 1*A*), large periapical lesions were noted upon follow-up (Fig. 1*B*). Resilon was advertised as more radiopaque than gutta-percha (29), so it is possible that the extreme radiopacity was masking areas of voids during obturation. However, not every Resilon-treated case developed a periapical lesion. Resolution of periapical lesions was noted as well (Fig. 1*D*).

Given the increased risk of nonhealing with Resilon cases, the question arises as to whether a "recall" of these cases would be indicated. We do not believe that this would be appropriate given that many Resilon cases did not have apical pathosis and because the practice adhered to standards of care at the time of treatment. We continue to encourage all patients to return for follow-up after treatment because lack of healing may occur in any endodontic case.

In this study, the variable of interest as well as several other important variables were assessed using bivariate and multivariate analyses. However, a limitation of the study was that systemic health, smoking history, periodontal health, and provider proficiency could not be easily downloaded and registered for each patient from the clinical system used at this institution and were not included in the analysis. For example, it is well recognized that systemic health may influence treatment outcomes (30). However, given the random assignment to each of the 2 groups of interest in this study, random selection of patients, and the uniform institutional protocols and standards used for treatment in the institution, it was assumed that these variables would generally be distributed equally. Furthermore, having an exhaustive list of confounding variables would generally require a larger sample size and should be the subject of future research.

Conclusion

Within the limitations of the study, the teeth that were obturated with Resilon were over 5-fold more likely to present with lesions at follow-up compared with gutta-percha obturated teeth, suggesting that there is no long-term benefit to using this material compared with gutta-percha in nonsurgical root canal treatment.

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The authors wish to dedicate this paper to the life and work of Dr. Harmeet Walia.

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